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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,221	02/06/2004	Elaine B. Levine	38-21 (52220)C	8169
27161	7590	09/15/2006		
MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167			EXAMINER SAUNDERS, DAVID A	
			ART UNIT 1644	PAPER NUMBER

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/774,221

Applicant(s)

LEVINE, ELAINE B.

Examiner

David A. Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

The amendment of 2/6/04 has been entered. Claim 15 is pending and under examination.

The disclosure is objected to because of the following informalities: At page 1, applicant must insert continuation data referring to parent application 09/951,470 and its current status.

Appropriate correction is required.

Claim 15 is objected to under 37 CFR 1.75 for failing to indent each step of the claimed method.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 15, lines 1-2 "in a biological sample and progeny thereof" can be read two ways. First, it can be read to mean that one is detecting the "event" in the "biological sample" (e.g. a plant produced by transformation and regeneration of a single plant cell), or that one is detecting the "event" in a sample plant that is a progeny of the transformed and regenerated plant. Second it can be read to mean that one is detecting the "event" in a biological sample (plant) and that such detection assures that the progeny of the sample plant will have the same "event". It is believed that applicant intends the former case. However, the grammatical structure of the claim points to the second case.

In claim 15, lines 3-4 "using an immunological method comprising antibody specific for..." is indefinite because an "immunological method" must be claimed in terms of process steps, not in terms of merely one of the reagents (i.e. "antibody specific for...") that might be used in an unrecited process step. That is, any "method" comprises process steps, not reagents used.

Finally, claim 15 is unclear because it is recited in a circular manner. The preamble calls for "detecting corn event MON810 in a biological sample" while step a)

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calls for "extracting protein from a sample of corn event MON810 tissue". It thus appears that, in conducting step a) one knows that the sample is one which has "corn event MON810". If one knows this, why conduct a method of detecting?

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

If one reads claim 15, lines 1-2 in the second of the two possible ways noted above under 112, second paragraph; then applicant has not enabled the detecting of an "event" in a biological sample (plant) such that the detection assures that the progeny of the sample plant will have the same "event". The progeny of the sample are subject to numerous possible genetic changes that may delete or suppress the event detected in the sample. For example, translocation of inserted "event MON810" DNA may suppress expression thereof. Also, not all progeny produced by outcrossing would be expected to inherit the inserted "Event MON810" DNA. For such reasons, one of skill would not expect that detecting an "event MON810" in a biological sample (plant) would predict or assure that the progeny of the sample plant will have the same "event".

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has given inadequate direction as to how one is to prepare an antibody used in step b) of the claimed method so that one would be able to particularly detect Corn Event MON810. As far as the examiner can determine from the disclosure, the plasmid for Corn Event MON810 was obtained by truncating the coding sequence for the Cry1Ab insecticidal protein contained the plasmid pMON17772. See para. [0043] of applicant's PG publication US 2004/0180373. By such truncation, only the 5' most 2448 base pairs encoding the Cry1Ab protein sequence are present in the plasmid for Corn

Event MON810 (see para. [0043]). One of skill would reasonably expect that, since the Corn Event MON810 insecticidal protein has an insecticidal activity like that of Cry1Ab, the N-terminal portion of Cry1Ab that is in common with the Corn Event MON810 protein would have essentially the same tertiary structure as that of the Corn Event MON810 protein. Therefore there would be a high likelihood that any antibody that binds to the Corn Event MON810 protein would also bind to or cross-react with a common epitope found also in the N-terminal portion of Cry1Ab that is in common with the Corn Event MON810 protein. Likewise, there would be a high likelihood that any antibody that binds to the Corn Event MON810 protein would also bind to or cross-react with a common epitope found also in the N-terminal portion of other insecticidal proteins that might have been similarly obtained as a truncated form of the Cry1Ab insecticidal protein. Applicant has not given the reader any direction as to how to make or shown any exemplification of an antibody that would specifically detect the Corn Event MON810 protein in a sample and not cross react with the N-terminal portion of the Cry1Ab protein or other truncated versions thereof.

The only portion of the Corn Event MON810 protein that one of skill might expect to be unique thereto is that encoded by the "six nucleotides immediately adjacent to the 3' end of the intended inserted sequence" (see para. [0043]). Applicant, however has not provided any direction as to whether the two amino acid residues encoded by these six nucleotides would, in conjunction with the Cry1Ab residues adjacent thereto form any immunogenic epitope, and if so, in what species of antibody producing animal.

Applicant has therefore left it to other to find out how to provide an antibody for use in the claimed method that would enable the detection of Corn Event MON810 protein. All <sup>r</sup>stating material required to conduct a method must be available as of the filing date. See Ex parte Moersch 104 USPQ 122.

Claim 15 is allowable over prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is


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571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 9/9/06 DAS

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
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